BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Predator Urines:
Coyote Urine
(PC Code 029007)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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I. Executive Summary

A predator urine, such as coyote urine, is classified as biochemical pesticide because: 1) this is an animal byproduct and, therefore, is considered a naturally-occurring substance and 2) when used as a repellent, has a "non-toxic" mode of action.

Coyote urine is the technical grade active ingredient (TGAI) formulated into the end-use product for the Shake Away® Deer Repellent Granules. This end-use product is intended to repel deer, elk, beavers, armadillos, javalina (peccary or boar), and domestic cats from residential yards and gardens. The specific component of the urine, which elicits the intended response is unidentified. The main components of the urine are water, urea, creatinine, sodium, potassium, chloride, phosphate, calcium, and magnesium.

Urine is commonly employed by certain vertebrate species as a part of animal behavior associated with indirectly asserting an animal's presence, such as in establishing a territorial area or in attracting members of the same species including potential mates. The scent of urine also allows competitors or potential prey species to respond by avoiding or at least in detecting the current or recent presence of the animal that has marked the area with their urine. This response to a specific scent associated with a species' urine is used by game hunters to mask the presence of the human scent. As such, masking human scent is not a pesticidal use. Trappers are also known to use coyote urine to attract coyotes to traps.

The Biopesticides and Pollution Prevention Division (BPPD) risk management decision regarding the registration of coyote urine is based on: 1) the TGAI is naturally occurring, 2) the product is applied for "non-food uses," 3) the TGAI as used in the end-use product does not require a tolerance, 4) the TGAI is not likely to be toxic to mammals or the environment when used according to label instructions, and 5) exposure to the product formulation is unlikely due to the design of the end-use product.

BPPD considered coyote urine in light of the form of product to be sold and the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has not identified any dietary or non-dietary exposure issues that may affect the U.S. population in general, including infants and children. The Agency has thereby determined that there is reasonable certainty that no harm will result from aggregate exposure to coyote urine residues, including dietary exposures and all other exposures for which there is reliable information.

II. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name: Coyote urine

Chemical Names: Not applicable

Trade & Other Names: Not applicable

CAS Registry Number: None assigned

OPP Chemical Code: 029007

Basic Manufacturer: Shake-Away
2330 Whitney Avenue
Hamden, CT 06518

B. USE PROFILE

Pesticide uses and application methods include the following:

Type of Pesticide: Biochemical pesticide; animal repellent

Use Sites: Residential gardens and yards (non-food)

Target Pests: Deer, elk, beavers, armadillos, javalina (peccary or boar), domestic cats

Formulation Type: Granules inside a low density polyethylene (LDPE) bag

Method and Rates of Application: The product formulation contained in separate bags (called packs) that are hung one pack for each 10 to 20 feet of the perimeter of the area to be protected by the predator scent. Squeezing the bag at first application and then again 4 to 6 weeks later helps to release scent from the product. The packs do not require opening or dispensing of the granular formulation inside during the 90 day period of use.

Timing: Packs are replaced every 90 days.

Use Practice Limitations: Label instructions state: DO NOT OPEN OR DISPERSE CONTENTS.

C. ESTIMATED USAGE

None used yet since this will be the first registered product.

D. DATA REQUIREMENTS

The Biopesticides and Pollution Prevention Division (BPPD) reviewed data requirements for granting this registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The product analysis, manufacturing process, and physical and chemical properties data requirements are adequately satisfied by the data submitted by the registrant for the technical grade active ingredient (TGAI) and end-use product (see Tables 1 and 2). The mammalian toxicology and ecological effects data requirements were satisfied by submission of data waiver requests supported by appropriate rationale and studies from literature. The Agency reviewed all of the data and waiver requests and determined that they adequately satisfy current guideline requirements. The Agency issued a product registration for Shake Away® Deer Repellent Granules (also as alternate brand name: Shake Away® Deer Repellent 90-Day Packs), EPA Registration Number 80917-1, on March 31, 2006. In granting this product registration, the Agency does not foresee any unreasonable adverse effects to humans and the environment from any of the uses of coyote urine when used as directed by the product labeling.

E. REGULATORY HISTORY

Shake Away submitted an application for the registration of Shake Away® Deer Repellent Granules, EPA Registration Number 80917-R, with the active ingredient coyote urine, on December 15, 2003. A notice of receipt of an application for registration of Shake Away® Deer Repellent Granules, containing coyote urine as the active ingredient, was published in the Federal Register on December 15, 2004 (69 FR 75063) with a 30-day comment period. Comments were received following publication of the Federal Register notice. The primary issue raised to the Agency's attention concerned the potential for disease spread to both humans and domestic animals through wildlife urine. Supporting information was provided as part of the comments concerning potential contamination of predator urine products with microbial and viral pathogenic organisms. The Agency in turn considered how the product's formulation was processed during manufacture and that the end-use product for the Shake Away® Deer Repellent Granules is contained in a low density polyethylene (LDPE) bag. The pack (bag) reduces or eliminates the potential for exposure due to the presence of pathogenic organisms in the granules. The packs are sealed upon manufacture and not intended to be opened when distributed, marketed, in use, or when disposed after use.

Coyote urine is a new active ingredient for a pesticide formulation. The registered end-use product is intended as a non-food use, biochemical repellent against deer, elk, beavers, armadillos, javalina (peccary or boar) and domestic cats. An unconditional registration for this active ingredient was issued on March 31, 2005.

F. CLASSIFICATION

On July 8, 2002, the Biochemical Classification Committee determined that predator urines can be classified as a biochemical pesticide due to their non-toxic mode of action as a repellent. The Committee recommended that all registrants be required to demonstrate that their product(s) derived from predator urine(s) are free of microbial and viral pathogens.

G. FOOD CLEARANCES/TOLERANCES

This end-use product registration is for non-food use and no food clearances or tolerances are required due to the non-food status of the current registered uses.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for registration of coyote urine when formulated into the end-use product Shake Away® Deer Repellent Granules are satisfied.

1. Product Identity and Mode of Action

a. Product Identity

The end-use product, Shake Away® Deer Repellent Granules contains 5.0% coyote urine as its active ingredient. Coyote urine is a yellow liquid with an ammonia-like scent. Urine is collected from domesticated coyotes (*Canis latrans*) raised in enclosed areas on a ranch. The major urine constituents are water (95%), urea, creatinine, sodium, calcium, phosphate, chloride, potassium and magnesium.

The description of the product's production process and the formation of impurities were examined by the Agency and are acceptable to meet current guideline standards. A preliminary analysis of coyote urine was conducted using five batches of the technical grade active ingredient (TGAI) and was determined to be acceptable. The analytical results are used for quality control and quality assurance. The analytical method is a high performance liquid chromatography (HPLC) method that involves quantitation (that is, determining the presence and size) of a specific marker peak on a chromatogram. A specific link between the chosen marker peak and the product's animal repellency is as yet undetermined. The peak's consistent presence (at a given elution time and with a relative peak height) on chromatograms generated by product analyses provides a measure for relative consistency in the product when manufactured over time, from batch to batch.

b. Mode of Action

The Shake Away® Deer Repellent Granules (Pack) is intended for use as an animal repellent. The urine inside the pack emits a scent that is associated with the presence of a coyote which in turn mimics the presence of a coyote in the area where the product is used. Target pests that detect the scent avoid the area where the product is placed.

2. Physical and Chemical Properties Assessment

The physical and chemical characteristics of coyote urine and Shake Away® Deer Repellent Granules were submitted to support the product's registration. The product chemistry requirements are summarized in Table 1. The physical and chemical properties of the technical

grade active ingredient (TGAI) and end-use product (EP), Shake Away® Deer Repellent Granules, are summarized in Table 2.

TABLE 1. Product Chemistry Data Requirements

OPPTS GUIDELINE NO.	STUDY	RESULTS	MRID NO.
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Submitted data satisfies the data requirements for product identity, manufacturing process, and discussion of formation of impurities	46312001
830.1700	Preliminary Analysis	Submitted data satisfy the data requirements for analysis of samples	46164701
830.1750	Certification of limits	Limits listed in the CSF are adequate / Acceptable	46312001
830.1800	Analytical Method	Acceptable	46164702

TABLE 2. Physical and Chemical Properties for Shake Away® Deer Repellent Granules

OPPTS Guideline Reference No./Property	Description of Result TGAI/EP[a]
830.6302 Color	Yellow / White
830.6303 Physical State	Liquid / Granules
830.6304 Odor	Ammonia-like / Ammonia-like
830.6313 Stability	Stable when stored in sealed containers at ambient temperature / Not required for EP
830.6314 Oxidation/Reduction: Chemical incompatibility	TGAI and EP do not contain oxidizing or reducing agents
830.6315 Flammability	TGAI and EP do not contain combustible liquids
830.6316 Explodability	TGAI and EP are not potentially explosive and do not have explosion characteristics
830.6317 Storage Stability	Not required for TGAI / Storage stability will be assessed by scent detection of five samples every three months for a 12-month period of time
830.6319 Miscibility	Not required for TGAI / Product is not an emulsifiable liquid and is not to be diluted with petroleum solvents
830.6320 Corrosion Characteristics	Not required for TGAI / Corrosion characteristics will be assessed by visual inspection of the packaging material at each

TABLE 2. Physical and Chemical Properties for Shake Away® Deer Repellent Granules	
OPPTS Guideline Reference No./Property	**Description of Result TGAI/EP[a]**
	test period of the storage stability study
830.6321 Dielectric Breakdown Voltage	Not required for TGAI / Product is not a liquid and is not intended for use around electrical equipment
830.7000 pH	9.5-10.1 / Product is a solid and is not dispersible in water
830.7050 UV/Visible	Not applicable: photochemical degredation of the TGAI is not expected when used for manufacturing / Not required for EP
830.7100 Viscosity	1 centipoises at 25°C / Not required for EP: product is not a liquid
830.7200 Melting Range	Not required for TGAI: TGAI is a liquid / Not required for EP
830.7220 Boiling Range	100°C at 1 atm / Not required for EP
830.7300 Bulk Density/Specific Gravity	1.015-1.045 / 2.5-2.75 lb/ft3 at 25°C; 2.7 -2.75 lb/gal
830.7370 Dissociation Constant in Water	TGAI is not ionic and is used for manufacturing only / Not required for EP
830.7520 Particle Size/Distribution	Not available
830.7550 Partition Coefficient	Not available
830.7840 Water Solubility	Not available
830.7950 Vapor Pressure	23.756 mm Hg at 25°C at 1 atm

[a] Data from MRID 46312001 and 46591303.

B. HUMAN HEALTH ASSESSMENT

Guideline requirements for mammalian toxicity data, to support the registration application for the Shake Away coyote urine product, are satisfied by submission of information with appropriate rationales to justify granting requests for waivers from the requirement of guideline studies. The Agency has determined that this a new biochemical pesticide product's use pattern qualifies as a non-food use.

1. Toxicology Assessment

Adequate mammalian toxicology data are available to support registration of Shake Away® Deer Repellent Granules, containing the new active ingredient coyote urine. No additional toxicological data are required at this time.

a. Acute Toxicity

Acute toxicity waiver request rationales are summarized below. This product is in Toxicity Category IV for acute oral, acute dermal, and acute inhalation toxicity and for primary eye and primary dermal irritation, and is not a dermal sensitizer. Based on the Agency's review of the information, rationale, submitted literature, and potential for exposure discussed in detail in this section of the BRAD, no additional toxicity data are required to support the non-food uses of this biochemical.

Adequate waiver request rationales were presented in MRIDs 46311602 and 46622401 (see Appendix B: References for MRID volume titles) for all Tier I toxicity data requirements (40 CFR 158.690(c)). Mammalian carnivore urine chemical constituents are primarily the same and can vary depending on various factors including age, diet, and health. The major constituents include water, urea, potassium, chloride and sodium. (Ganong, 2003). A study discussing an analysis of urinary components of Alaskan sled dogs (Hinchcliff, 1997) was compared to an analysis of the technical grade active ingredient performed by the College of Veterinary Medicine of Cornell University (MRID 46311602). The urines were very similar in composition, containing the same constituents with the exception of the coyote urine, which contained magnesium, which was not mentioned in the Hinchcliff study. Coyote urine osmolality was approximately ten percent that of the dog urine. Consequently the coyote urine was more dilute, containing less solutes than the dog urine. Urine is ubiquitous in nature, and all of the identified components naturally occur in the environment. Urea and water are on the Agency's List 4a: Inerts of Minimal Concern.

Exposure to the active ingredient is not likely because the granules are contained in a LDPE bag during storage, use and disposal.

b. Mutagenicity and Developmental Toxicity

Requested waivers of the mammalian mutagenicity and teratogenicity data requirements were granted by the Agency because of the low toxicity of the active ingredient and minimal likelihood of exposure. The components of the technical grade active ingredient are not structurally related to any known mutagen or belong to any chemical class of compounds containing known mutagens.

c. Subchronic Toxicity and Immunotoxicity

Waivers requested for the subchronic and immunotoxicity study requirements were granted by the Agency because of the low toxicity of the active ingredient and minimal likelihood of exposure. The subchronic studies (90-day feeding (OPPTS 870.3100), 90-day dermal (OPPTS 870.3250), and 90-day inhalation (OPPTS 870.3465)) are not required.

d. Chronic Exposure and Oncogenicity Assessment

Repeated dose studies are conditionally required if the potential for adverse chronic effects are indicated based on: 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required only if the active ingredient or any of its metabolites, degradation products, or impurities produced in Tier I studies any morphologic effects in any organ that potentially could lead to neoplastic changes. None of the submitted information triggered the need for chronic exposure or oncogenicity testing.

e. Effects on the Endocrine System

The US Environmental Protection Agency (Agency) is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by Food Quality Protection Act, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.”

Endocrine system-related effects from use of coyote urine are not expected: 1) due to the containment of the formulation inside of the product’s packaging and thus reducing the potential for exposure, and 2) coyote urine is not a known endocrine disruptor nor is it, or any of its components, related to any known endocrine disruptors.

f. Elimination of Microorganisms

Exposure to the end-use product’s granules, containing coyote urine, when contained inside of the sealed LDPE bag (product pack) is not likely. Further, during the course of product

manufacturing steps are taken to reduce or remove potential pathogens. After the urine is collected, the liquid is next pumped through a 1 mm stainless steel screen, poured into a bulk container, poured through two layers of 100 micron nylon filter and then pumped through a 5 micron pressure filter. The urine is then pasteurized at 165°F (73.9°C) for one minute. At this time, the Agency is not requiring additional testing to detect the presence of potential pathogens following these manufacturing steps due to the nature of the product's sealed outer container.

2. Dose Response Assessment

No toxicological endpoints were identified. A dose response assessment is not required.

3. Dietary Exposure and Risk Characterization

There will be no dietary exposure when the product is used according to label directions.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

Shake Away® Deer Repellent Granules are intended for residential use only. No occupational exposures are expected for the registered product.

b. Residential, School and Day Care Exposure and Risk Characterization

The end use product containing coyote urine is intended for use in a residential setting. Because the active ingredient is naturally occurring, possesses a non-toxic mode of action, and is contained in a sealed package the Agency is not concerned about the potential exposure to children when the end-use product is used according to label directions.

5. **Drinking Water Exposure and Risk Characterization**

Drinking water exposure will not occur if the end-use product is used according to label instructions.

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that the Agency shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless the Agency determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. Based on all the available

information, the Agency concludes that there is reasonable certainty that no harm to infants and children or adults will result from the use of coyote urine in Shake Away® Deer Repellent Granules due to a lack of exposure (non-food use) when the product is used according to approved labeling.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

There is reasonable certainty that no harm to the US population will result from aggregate exposure to coyote urine. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity and unlikelihood of exposure when the product is used according to approved labeling.

8. Cumulative Effects

When used as proposed, Shake Away® Deer Repellent Granules are not expected to result in coyote urine residues at levels that are of toxicological concern. Because of the low inherent toxicity of the active ingredient and that it is retained in a sealed bag, no cumulative effect with other toxins is anticipated.

9. Risk Characterization

The Agency considered human exposure to coyote urine in light of the relevant safety factors in FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of Shake Away® Deer Repellent Granules when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

Non-target organism studies (40 CFR 158.690(d)) were not submitted. In lieu of studies, the registrant submitted waiver requests supported by information presented in MRIDs 46311602 and 46622401. This information is similar to what was submitted as part of the rationale for waiving the mammalian toxicity requirements.

Adequate data waiver requests and supporting rationales were presented for all Tier I ecotoxicity data requirements (40 CFR 158.690(b). A study discussing an analysis of urinary components of Alaskan sled dogs (Hinchcliff, 1997) was compared to an analysis of the technical grade active ingredient as performed by the College of Veterinary Medicine of Cornell University (MRID 46311602). The urines were very similar in composition, containing the same constituents with the exception of the coyote urine, which contained magnesium, which was not mentioned in the Hinchcliff study. Coyote urine osmolality was approximately ten percent that of the dog urine.

Consequently the coyote urine was more dilute, containing less solutes than the dog urine. Urine is ubiquitous in nature and all of the identified components naturally occur in the environment. Urea and water are on the Agency's List 4a: Inerts of Minimal Concern.

Waiver requests were granted by the Agency due to the fact that the technical grade active ingredient will be retained in a sealed LDPE bag throughout distribution, marketing, storage, use, and disposal.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered. Risk to non-target species is minimal due to the use pattern, application methods, and lack of toxicity.

3. Ecological Exposure and Risk Characterization

The potential for exposure to non-target wildlife is unlikely due to the use patterns and design of the end-use product; although it is noted that coyotes might be attracted to areas where the product is used.

D. EFFICACY DATA

Efficacy data were not submitted and are not required.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)5) of FIFRA provides for the registration of new active ingredients if it is determined that: A) its composition is such as to warrant the proposed claims for it; B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; C) it will perform its intended function without unreasonable adverse effects on the environment; and D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion "A" above, coyote urine products, when retained in a sealed container are not expected to cause unreasonable adverse effects when used according to label instructions. Criterion "B" is satisfied by the current label and the data presented in this document. The Agency believes that this pesticidal active ingredient will not cause any unreasonable adverse effects, is a repellent, is already ubiquitous in nature, and exposure to the active ingredient is unlikely. Criterion "C" and "D" are satisfied by the data presented in the registration application of this biochemical. Therefore, coyote urine is eligible for registration.

B. REGULATORY POSITION

1. Unconditional Registration

All of the data requirements are fulfilled and BPPD granted an unconditional registration for the active ingredient, coyote urine.

Tolerance Establishment

The uses of coyote urine are determined to be "non-food" uses and therefore do not require the establishment of a food tolerance or an exemption from the requirements of a tolerance.

2. CODEX Harmonization

Not applicable because all of the uses have been determined to be non-food.

3. Nonfood Registrations

There are no issues at this time.

4. Risk Mitigation

There are no significant risk issues identified for dietary risk, residential risk, or ground and surface water contamination.

5. Endangered Species Statement

Based on the information discussed above, the Agency has determined that use of Shake Away® Deer Repellent Granules containing 5.0% coyote urine as its active ingredient, will **Not Adversely Affect (NAA)** threatened and/or endangered species. When the product is used according to label use directions, there are no concerns for any non-target organisms. The product acts as a repellent to most mammalian species, does not affect insects or plants, is not used on aquatic sites, and is only attractive to other coyotes and other canine species.

C. LABELING RATIONALE

The Agency's position is that the labeling for this product, Shake Away® Deer Repellent Granules, containing coyote urine as the active ingredient, complies with current pesticide labeling requirements imposed under FIFRA and 40 CFR ' 156.10.

1. Human Health Hazard

a. Worker Protection Standard

The End-Use Product does not come under the provisions of the Worker Protection Standards (WPS).

b. Non-Worker Protection Standard

There are no non-worker (non-mixer/loader/applicator) human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for coyote urine and concludes that the precautionary labeling (i.e., Signal Word, First Aid statement, and other label statements) listed on the label (See Appendix A - Product Label) adequately mitigate the risks associated with the currently registered uses.

d. Spray Drift Advisory

No spray drift advisory statement is necessary for this proposed use.

2. Environmental Hazards Labeling

For terrestrial uses: Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate.

3. Application Rate

The end-use product comes with twist ties and four packs in the end-use product retail package. Each pack is hung every 10 to 20 feet around the area, such as a garden or yard, to be protected by the repellent product. The label instructs the user to suspend each pack approximately 2 to 4 feet above the ground. For continued use, the packs are to be replaced every 90 days.

D. LABELING

Product name: **Shake Away® Deer Repellent Granules**

Active Ingredient:

Coyote Urine.....5.0%

Other Ingredients.....95.0%

Total 100.00%

Signal word is "CAUTION".

The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (CAUTION)

V. Actions Required by Registrants

There are no data requirements, label changes or other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

The Agency evaluated all of the data submitted in connection the initial registration of coyote urine and determined that these data are sufficient to satisfy current registration guideline requirements. Therefore, the product, Shake Away® Deer Repellent Granules, EPA Registration Number 80917-1, is eligible for registration. No additional data are required to be submitted to the Agency at this time.

Not withstanding the information stated in the previous paragraph, it should be clearly understood that certain, specific, data are required to be reported to the Agency as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

A. REPORTING OF ADVERSE EFFECTS

Reports of all incidents of adverse effects to humans or domestic animals (including both suspected and confirmed incidents) must be submitted to the Agency under the provisions stated in FIFRA, Section 6(a)(2).

B. REPORTING OF HYPERSENSITIVITY INCIDENTS

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.690(c), guideline reference number 152-16.

VI. Appendix A

Table 5 lists the use sites for the product. The label for the product is also attached (see **Appendix B)**.

Table 5. Use Sites	
Shake Away Deer Repellent Granules Residential: gardens and yards	**Official date registered:**

Label Language Requirements

The following labeling language as listed below is required for Federal registration.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals. Caution. Harmful if swallowed. Avoid contact with mouth, skin, or eyes. Wash hands before eating, drinking, chewing gum, using tobacco, or using bathroom facilities.

Environmental Hazards: For terrestrial uses: Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate.

FIRST AID:

If inhaled:
Call a poison control center or doctor for further treatment advice.
Have person sip a glass of water if able to swallow.
Do not induce vomiting unless told to do so by the poison control center or doctor.
Do not give anything by mouth to an unconscious person.

If on skin or clothing
Take off contaminated clothing.
Rinse skin immediately with plenty of water for 15-20 minutes.
Call a poison control center or doctor for treatment advice.

If in eyes:
Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
Call a poison control center or doctor for treatment advice.

The following statement must accompany the First Aid text block: "Have the product container or label with you when calling a poison control center or doctor, or going for treatment." The Agency guidance also suggests including a contact telephone number for additional emergency medical treatment information.

Use Directions:

The Directions for Use pertaining to hanging the end-use product packs states the following:

"DO NOT OPEN PACKS OR DISPERSE CONTENTS."

Appendix B

REFERENCES

Ganong WF, editor. (2003) Review of Medical Physiology, 21st Edition. Chapter 38. Renal Function & Micturition. Lange Medical Books, McGraw-Hill, New York. Table 38-5, p 713.

Hinchcliff KW, Reinhart GA, Burr JR, Swenson RA. (1997) Exercise-associated hyponatremia in Alaskan sled dogs; urinary and hormonal responses. J. Appl. Physiol. 83(3): 824-829

Study Information Submitted For Product Registration - 80917-R

MRID	Citation
46164700	Shake Away (2003) Submission of Product Chemistry Data in Support of the Application for Registrations of SA Deer Repellent Granules, SA Deer Repellent 90-Day Packs, SA Cat Deterrent Granules, SA Small Critter Granules, SA Rodent Repellent Granules, SA Squirrel Repellent 90-Day Packs and SA All Purpose Repellent Granules. Transmittal of 2 Studies.
46164701	Askins, C. (2003) Predator Urine Active Ingredient Characterization HPLC Fingerprint: Project Number: 0313110, SAMPLE/PREDATOR, SA2003/01. Unpublished study prepared by Life Sciences Labs., Inc. 55 p.
46164702	Askins, C. (2003) Active Ingredient - Shake-Away Products, HPLC Fingerprint Analytical & Enforcement Methods. Project Number: 314823, SA2003/02, SAMPLE/PREDATOR/LIQ. Unpublished study prepared by Life Sciences Labs Inc. 36 p.
46221600	Shake-Away (2004) Submission of Product Chemistry Data in Support of the Applications for Registrations of Deer Repellent Granules, Deer Repellent 90-Day Packs, Cat Deterrent Granules, Small Critter Granules, Rodent Repellent Granules, Squirrel Repellent 90-Day Packs, and All Purpose Repellent Granules. Transmittal of 1 Study.
46221601	Askins, C. (2003) 30 Day Product Stability & Container Corrosivity Study: Shake Away Animal Repellent Products. Project Number: 314823, 316070. Unpublished study prepared by Life Sciences Laboratories, Inc. 54 p.
46312000	Shake-Away (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Shake-Away Deer Repellent Granules. Transmittal of 1 Study.

46312001	Roberts, A. (2004) Product Chemistry for Shake-Away Deer Repellent Granules. Unpublished study prepared by SHAKE-AWAY. 42 p.
46409500	Shake-Away (2004) Submission of Product Chemistry Data in Support of the Application for Registrations of Shake-Away Deer Repellent Granules, Shake-Away Critter Repellent Granules and Shake-Away All Purpose Repellent Granules. Transmittal of 1 Study.
46409501	Askins, C. (2004) Product Stability and Container Corrosivity of Shake-Away Animal Repellant Products. Project Number: 316071, 316074. Unpublished study prepared by Life Sciences Laboratories, Inc. 87 p.
46591300	Shake-Away (2005) Submission of Product Chemistry and Safety Data in Support of the Applications for Registration of Shake-Away Deer Repellent Granules, Shake-Away Critter Repellent Granules and Shake-Away All Purpose Repellent Granules. Transmittal of 4 Studies.
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46591303	Roberts, A. (2005) Supplemental Product Chemistry Information for Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Technology Sciences Group, Inc. 23 p.
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46622400	Shake-Away (2005) Submission of Product Chemistry Data in Support of the Application for Registrations of Shake-Away Deer Repellent Granules, Shake-Away Critter Repellent Granules and Shake-Away All Purpose Repellent Granules. Transmittal of 1 Study.
46622401	Mileson, B. (2005) Supplemental Product Identity and Composition Information for Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Cornell University and Technology Sciences Group, Inc. 54 p.

Appendix C

Product Label

Text pesticide label without graphics, pictures or illustrations

Shake-Away® Deer Repellent Granules

(Alternate Brand Names: Shake-Away® Deer Repellent 90-Day Packs)

Active Ingredient:
Coyote Urine..... 5.00%
Other Ingredients: 95.00%
Total: 100.0%

Keep Out of Reach of Children

CAUTION

See (back panel) (insert label) (insert instructions) for (additional) Precautionary Statements and Directions for Use.

EPA Reg. No.: (pending as File Symbol 80917-R)
EPA Est. No.:

Net Contents: XX oz. (XX grams).

Manufactured by:
Shake-Away
2330 Whitney Avenue
Hamden, CT 06518
www.shake-away.com
toll-free: 1-800-517-9207

FIRST AID	
If swallowed	• Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. (In the U.S.) You may also contact 1-800-222-1222 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals. Caution: Harmful if swallowed. Avoid contact of mouth, skin, or eyes. Wash hands before eating, drinking, chewing gum, using tobacco or using bathroom facilities.

ENVIRONMENTAL HAZARDS

Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General:

Animals use urine to communicate in the wild. When they repeatedly smell a predator's odor, animals conclude it's a "dangerous" place and choose instead to move elsewhere. Shake-Away® Deer Repellent Granules uses the same laws of nature to protect your yard and garden. Shake-Away® Deer Repellent Granules creates the illusion that coyotes are present in your lawn or garden.

Use Shake-Away® Deer Repellent Granules to repel:

Deer
Elk
Beavers
Armadillos
Javalina
Domestic Cats

Application Directions:

- One application lasts 90 days.

- Shake-Away® Deer Repellent 90-Day Packs kit contains: Four Shake-Away® Deer Repellent 90-Day Packs, two twist ties for hanging.

Use Restrictions – This product is not for direct application to plants intended for human consumption (i.e. food plants). Apply only to the perimeter of where food plants are grown.

Hanging -
Hang one pack every 10 to 20 feet around your garden or flowerbed perimeter, ensuring there is a pack on every outside corner. Suspend each pack approximately 2 to 4 feet above ground. For best results on isolated trees and bushes, consider hanging one or two packs on each bush or tree. DO NOT OPEN PACKS OR DISPERSE CONTENTS.

Replacing -
Replace each pack 90-Day Pack after 90 days. When replacing, hang the new pack in the same location.

Allow up to two to three weeks for Shake-Away® Deer Repellent 90-Day Packs to take full effect.

Helpful Hints -
Better results will be experienced if the pack is squeezed a few times when first applying, and then every four to six weeks thereafter.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Storage: Store in a cool, dry place
Disposal: Dispose of sealed pack by placing in the trash. Do not reuse pack.

(Warranty Statement)